

## **REMARKS**

### **I.     Status of Claims**

Claims 1, 3, 4, 6, 7, 9-30 and 32-55 are pending in the application. Claims 48 and 50-55 stand allowed, and claims 1, 3, 4, 6, 7, 9-30, 32-47 and 49 stand rejected under 35 U.S.C. §112, first paragraph, 35 U.S.C. §112, second paragraph, and 35 U.S.C. §102(b). The specific grounds for rejection are set out in detail below

### **II.    Drawings and Sequences**

The examiner has objected to the drawings submitted on September 6, 2001. Applicants believe that the submission was in error, and a new set of drawings conforming to “set A” are included herewith.

The specification is said to be defective in lacking inclusion of all proper sequence identifiers. Amendments have been provided adding sequence identifier where they are believed to be needed.

### **III.   Objections**

Applicants apologize for the improper numbering of the claims provided in the Preliminary Amendment filed on January 27, 2003, which was caused by an auto-numbering program.

Claims 4, 7 and 10 have been canceled, thereby obviating the objection to those claims. Reconsideration and withdrawal of the objections is respectfully requested.

#### IV. Rejections

##### A. 35 U.S.C. §112, First Paragraph

Claims 1, 3, 4, 6, 7, 9, 10, 12-15 and 18-30 are rejected as lacking a proper written description in the specification. Applicants traverse.

The examiner correctly points out that many of the claims are generic. In support of these generic claims, as acknowledged by the examiner, applicants can point to murine and human homologs of the Osterix polypeptide and gene. In addition, the claimed polypeptides/DNA segments are said to each contain a transactivation domain, a zinc finger domain and a proline rich domain. The examiner, without any particular comment on these structures, simply concludes that the specification provides insufficient information on “identifying characteristics” of these molecules.

The examiner’s reasoning seems to be that “the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of Osterix polypeptides.” Applicants presume, from the context of the action, that the “detailed chemical structure” referred to is a DNA or protein sequence. While it is true that not all of the claims contain a reference to a specific sequence (though many do), the claims and specification as presented provide far more than “a mere statement that [the Osterix polypeptide] is part of the invention.” Rather, the claims provide a structural description of the features of an Osterix polypeptide, and further embellish this with partial sequences in certain dependent claims. Thus, it is quite false to state that “there is no description of the specific structure that defines the genus as claimed ....”

Moreover, each of the cases cited by the examiner is easily distinguished. In *Fiers*, the relevant issue was the ***total absence of any sequence information in the relevant application***. Moreover, it addressed conception, not written description. In *Fiddes*, only a single species of

FGF was provided – here, there are two species of Osterix polypeptides. In *Amgen*, the issue was how broad the generic scope should be, and a complete proscription on generic claiming was not advanced. Here, where applicants have provided structural (though not sequential) characteristics in their broadest claims, a casual reference to *Amgen* is not sufficient to bring that decision to bear.

More recent written description cases stated that “the failure of the patent to describe the claimed sequences by anything other than their function” is problematic, but that the proper standard varies depending on the invention and whether it can be described in more than a functional way. See, e.g., *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 285 F.3d 1013 (Fed. Cir. 2002). The *Enzo* court stated that “the disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter of the claim.” The important point here is that function alone cannot support a set of claims to molecules behind that function. However, by the same token, this decision does *not* set up a proscription against the generic claiming of biological molecules. In this regard, it is thus of utmost importance to note that the present claims and specification do not rely on function alone to define Osterix. Rather, specific examples from two animals are provided, and structural features are included in the claims. As stated in MPEP §2163, an “objective [of §112] is to put the public in possession of what the applicant claims as the invention.” Clearly, claim 1 defines subject matter which can be identified. The fact that it may be broad is not dispositive.

Effectively, the examiner has not presented a sufficient basis for establishing, as a *prima facie* matter, that the instant claims lack written description. The facts of the cases cited by the examiner differ sufficiently from those presented here that the burden has not shifted to applicants to defend their claims. Rather, the mere generic nature of some claims, and the mere

lack of sequence information in a few, does not render them inconsistent with the controlling written description law. In light of the foregoing, applicants respectfully request reconsideration and withdrawal of the rejection.

***B. 35 U.S.C. §112, Second Paragraph***

Claim 1 is rejected over use of the term “Osterix polypeptide.” This rejection parallels that set out above with regard to written description. It is black letter law that applicants are permitted to be their own lexicographers, and have provided sufficient information, as noted by the examiner, to define the metes and bounds of the genus “Osterix polypeptide.” Moreover, it should be pointed out that no claim merely recites “Osterix polypeptide,” but at least recites other structural features such as a transactivation domain, a zinc finger domain and a proline rich domain. Further information, including specific sequences for Osterix polypeptides, are provided in the specification. As such, it is believed that one of skill in the art would be well apprised of the definition of an “Osterix polypeptide,” and thereby find the term both clear and definite.

Claims 12-15 are rejected as depending from canceled claim 5. Amendments have been provided correcting the dependency of these claims.

Claim 49 is rejected as allegedly lacking antecedent basis for the term “the coding sequence.” Applicants traverse, but an amendment has been provided, thereby obviating the rejection.

Claim 32 is rejected over the terms “standard hybridization conditions” and “stringent hybridization conditions.” Applicants traverse, but the claim has been canceled, rendering the rejection moot.

**C. Double-Patenting**

Claims 11 and 16 are rejected as being substantial duplicates of each other. Applicants traverse, but claim 16 has been canceled, thereby obviating the rejection.

**D. 35 U.S.C. §102(b)**

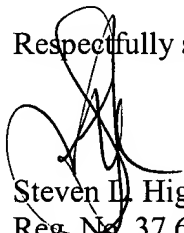
Claims 32, 33 and 40-46 stand rejected under §102(b) anticipated by Marra *et al.* Applicants have canceled the claims, thereby rendering the rejection moot.

**V. Conclusion**

In light of the foregoing, applicants respectfully submit that all claims are in condition for allowance, and an early notification to that effect is earnestly solicited. Should Examiner McKelvey have any questions regarding this response, a telephone call to the undersigned is invited.

Please date stamp and return the accompanying postcard to evidence receipt of these documents.

Respectfully submitted,

  
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